AD)				

Award Number: W81XWH-10-1-0889

TITLE: Biomarkers for Autism and for Gastrointestinal and Sleep Problems in Autism

PRINCIPAL INVESTIGATOR: George M. Anderson, Ph.D.

CONTRACTING ORGANIZATION: Yale University

New Haven, CT 06520-8047

Á

REPORT DATE: October 201G

Á

TYPE OF REPORT: Annual

Á

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

data needed, and completing this burden to Department of 4302 Respondents should be	and reviewing this collection of in Defense, Washington Headquar De aware that notwithstanding an De aware that notwithstanding an Defense aware that notwithstanding and Defense aware that notwithstanding aware that Defense aware that notwithstanding aware the Defense aware that notwithstanding aware the Defense aware Defense aw	nformation. Send comments reg ters Services, Directorate for Info	arding this burden estimate or a rmation Operations and Reports n shall be subject to any penalty	ny other aspect of this co s (0704-0188), 1215 Jeffe	lillied existing data sources, gathering and maintaining the illection of information, including suggestions for reducing rison Davis Highway, Suite 1204, Arlington, VA 22202- a collection of information if it does not display a currently
valid OMB control number. P 1. REPORT DATE	<u>LEASE DO NOT RETURN YOU</u>	IR FORM TO THE ABOVE ADD 2. REPORT TYPE	RESS.		
October 201G		2. REPORT TYPE Annual			ATES COVERED September 2011 – 29 September 201G
4. TITLE AND SUBTI		Amidai			CONTRACT NUMBER
Biomarkers for Au	itism and for Gastro	intestinal and Sleep	Problems in Autisr	• • • • • • • • • • • • • • • • • • • •	GRANT NUMBER
		•			31XWH-10-1-0889
				5c.	PROGRAM ELEMENT NUMBER
6. AUTHOR(S)				Ed	PROJECT NUMBER
6. AUTHOR(5)				5u.	PROJECT NUMBER
George M. Anders	son			5e. '	TASK NUMBER
Coorgo W. 7 maon	5011				
				5f. \	WORK UNIT NUMBER
E-Mail: george.ander					
7. PERFORMING OR	GANIZATION NAME(S)	AND ADDRESS(ES)			ERFORMING ORGANIZATION REPORT
Yale University				l N	UMBER
New Haven, CT 0	6520-8047				
Trow Haven, or o	0020 0011				
		NAME(S) AND ADDRES	S(ES)	10.	SPONSOR/MONITOR'S ACRONYM(S)
•	al Research and Ma	teriel Command			
Fort Detrick, Mary	land 21702-5012				
					SPONSOR/MONITOR'S REPORT
				'	NUMBER(S)
12 DISTRIBUTION /	AVAILABILITY STATE	/FNT			
	lic Release; Distribu				
''	,				
13. SUPPLEMENTAR	Y NOTES				
14. ABSTRACT					
No data analyses	ware planned or be	u a baan namfammad	to data and thus no	e findings are re	an auto d
No data analyses	were planned or na	ave been performed	to date and thus no	o illidings are re	eportea.
45 OUD 1507 75011	<u>. </u>				
15. SUBJECT TERMS		S, AUTISM, SLEEP,	gastrointestinal		
	Citilit, IODDLLING	,, , to Figure, OLLLI,	gaotronitootiilai		
16. SECURITY CLAS	SIFICATION OF:		17. LIMITATION	18. NUMBER	19a. NAME OF RESPONSIBLE PERSON
. J. JEJJKII I JEAJ	JOAHOH OI .		OF ABSTRACT	OF PAGES	USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE	1		19b. TELEPHONE NUMBER (include area
U	U	U	UU	ÁÁ	code)

REPORT DOCUMENTATION PAGE

Form Approved OMB No. 0704-0188

Table of Contents

	<u>Page</u>
Introduction	4
Body	4
Key Research Accomplishments	4
Reportable Outcomes	4
Conclusion	4
References	4
Appendices	4

Introduction

The objective of the proposed research is to compare the production of melatonin by young children with autism (N=45) to typically developing children (N=45). Specifically, we will see if the nighttime excretion rate of melatonin sulfate is markedly lower in the children with autism, whether there is a subgroup of children with autism having very low excretion; whether low nighttime excretion of melatonin sulfate is associated with sleep problems; and whether low daytime melatonin sulfate excretion is associated with gastrointestinal problems.

Body

Due to slower than anticipated recruitment over Year 1, we simplified the study in Year2 Quarter1 by collecting one daytime diaper and one overnight diaper (instead of two daytime diapers and one overnight diaper) and have condensed the questionnaire and instructions to one page. We have also made arrangements to approach subjects during visits to the Yale Child Study. We expected that these changes would enable us to recruit 2-4 subject per month for the remainder of the study. All appropriate approvals were obtained from the Yale Human investigation Committee.

Over the Year 2 period we have recruited a total of 28 subjects. Quarterly totals of autism and control (A & C) subjects recruited were Q1, 1 & 2; Q2 4 & 5; Q3 4 & 3; Q4 4 & 5.

- (4) Section III Problem Areas
 - (a) Current problems:

Recruitment rates have improved, but are still lower than planned.

(b) Anticipated problems and corrective action planned:

Increased recruitment efforts will be applied. This will include recruitment through word-of-mouth at local day-care centers for typically developing control subjects.

Key Research Accomplishments: None

Reportable Outcomes: None

Conclusions: None

References: None

Appendices: None